

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1575]

DMB

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Certifier	S. Reese

Agency Information Collection Activities; Proposed Collection; Comment Request; Nutrition Labeling; Declaration of Caloric Amounts and Serving Sizes for Breath Mints

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements regarding the nutrition labeling of breath mints.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Nutrition Labeling; Declaration of Caloric Amounts and Serving Sizes for Breath Mints—
21 CFR 101.9(b) and 101.9(c)(1) (OMB Control Number 0910-0364)—Extension**

Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)) requires that the label or labeling of a food bear nutrition information, including information on: (1) The serving size and number of servings per container, and (2) the number of calories present

in a serving of the food. Under FDA's nutrition labeling regulations in § 101.9(d)(3) (21 CFR 101.9(d)(3)), the nutrition facts panel of the food label must disclose the serving size of the food product and the number of servings in each package. Under § 101.9(c)(1), the nutrition facts panel must disclose the number of calories present in a serving of the food.

In the **Federal Register** of December 30, 1997 (62 FR 67775), FDA published a proposed rule to amend the nutrition labeling regulations by changing the label serving size for the product category "Hard candies, breath mints" to one unit. FDA proposed this change in response to a petition to provide a serving size for breath mints that more accurately reflects the amount customarily consumed per eating occasion. In a related issue, FDA also proposed to: (1) Modify the rounding rules for calories to allow the declaration of caloric amounts of less than 5 calories on the nutrition label, and (2) require that the number of calories declared on the nutrition label of a food product be consistent with any claims about caloric content that are made in its labeling. As a result of this proposed rule, manufacturers, packers, or distributors who make labeling claims that their products contain between 1 and 5 calories would be required to change the declaration of the amount of calories on the nutrition label. In addition, manufacturers of small breath mints would be required, under § 101.9(b), to change the serving size and, under § 101.9(c) and (d), to modify the amounts and Daily Values for nutrients listed in the nutrition label for their products. The proposal included burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations.

FDA estimates the burden of this collection of information as follows:

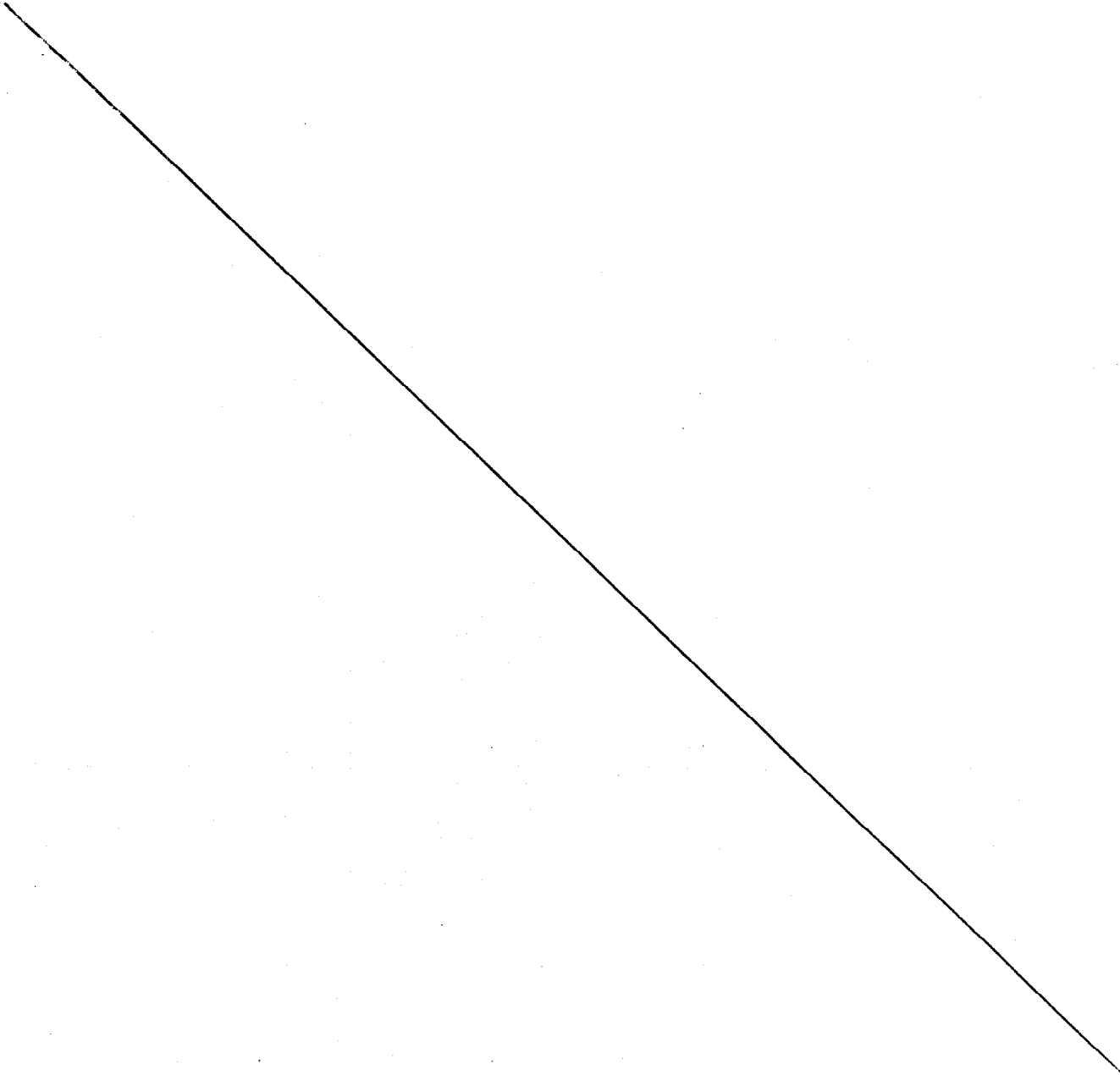
TABLE 1.—ESTIMATED ADDITIONAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Total No. of Responses	Hours per Response	Total Operating Costs	Total Hours
101.9(b) and (c)(1)	4	30	1	\$15,000	30

¹ There are no capital or maintenance costs associated with this collection of information.

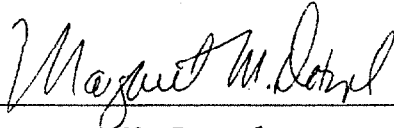
The proposed modification of the rules for the declaration of the amount of calories and the proposed change of the label serving size on the nutrition facts panel would result in a one-time burden created by the need for firms to revise their labels. In addition to changing the statement

of calories and the serving sizes, firms would have to recalculate the number of servings per container and any nutrient amounts and Daily Values affected by the change in serving size. Of those breath mints for which FDA has information regarding the size of the product, there are 4 firms producing 5 brands of small breath mints, or approximately 30 distinct small breath mint labels. These are the only firms that would be affected by this proposed rule. FDA estimates that these firms would require an average of 1 hour per label to comply with the requirements of a final rule based on this proposal. For breath mint products, the average administrative, redesign,



and inventory disposal costs for a labeling change of this type, with a 1-year compliance period, would result in a one-time operating cost of \$500 per label or a total estimated operating cost of \$15,000.

Dated: November 28, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

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